

Good morning Chairwoman Eshoo, Ranking Member Guthrie and Members of the Committee. My name is Phyllis Arthur and I am the Vice President of Infectious Diseases and Emerging Science Policy at the Biotechnology Innovation Organization, or BIO. Thank you for the opportunity to share our thoughts on the topic of enhancing public health through vaccine legislation.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. Our members are pioneering innovations in human health, food and agriculture, and industrial and environmental applications. BIO represents developers and manufacturers of both existing and new vaccines.

BIO vaccine members are fiercely committed to bringing life-saving vaccines to people of all ages across their lives. Vaccine manufacturers work in partnership with other companies, federal agencies, and clinicians to conduct research to the highest standards, making safety as well as efficacy and quality, the cornerstones of their development efforts. But our members also view themselves as a vital part of the national and global public health infrastructure system. This is why we are so honored to be part of this panel today.

Vaccines are the cornerstone of preventive medicine and public health. Over the last 50 years, vaccines have reduced or even eliminated the impact of diseases such as measles, rotavirus, hepatitis B, hepatitis A, influenza, and human papillomavirus just to name a few. The Centers for Disease Control and Prevention (CDC) has published data stating that pediatric vaccines given between 1994 and 2018 through the Vaccines for Children (VFC) program will prevent over 400 million illnesses, 27 million hospitalizations, and over 936,000 deaths. In addition, these high levels of pediatric vaccination can save the U.S economy over \$1.9 trillion in societal costs, including \$406 billion in direct healthcare costs¹.

Over the last year we have also learned the importance of vaccines for adults, particularly for older adults. Our national experience combatting the SARS-CoV-2 pandemic, which has killed almost 600,000 Americans and put millions in the hospital, demonstrates the powerful impact of uncontrolled infectious diseases. But the successful development and deployment of vaccines as part of our national COVID-19 pandemic response is an example of what can be achieved when the government, medical professionals, public health, industry and community organizations work together.

We all know that vaccines save lives but our most valuable lesson from this last year is that vaccines coupled with **vaccination** is truly lifesaving. Responding to the pandemic taught us several key lessons. First, our national public health infrastructure is not only vital in "normal" times, it is the backbone of our pandemic response and recovery system. Investing in this infrastructure by increasing

¹ www.cdc.gov/features/vfcprogram

support for state, local, and territorial health departments and state data systems, like immunization registries, can help track immunization uptake, ensure individuals receive all of their necessary doses, and help restore our routine immunization rates before the school year begins again. Given the precipitous drop we have seen in pediatric, adolescent and adult routine immunization, a focus on reinvigorating our public health systems is crucial to avoid outbreaks of other outbreaks from vaccine-preventable diseases over the coming months. A bill like H.R. 550, the Immunization Infrastructure Modernization Act, which seeks to modernize the data collection, reporting, and security capabilities of our state immunization registries can help accomplish these goals. Passage of this bill will help states better manage important public health data on routine immunizations for children, adolescents, and adults. But it will also enhance our ability to respond better to outbreaks of vaccine-preventable diseases as well responses to future pandemics. BIO supports all efforts to strengthen these data systems.

Our second valuable lesson was that educational efforts about the value and impact of vaccines on our health and our economy should be a continuous effort. Many organizations, including BIO, partnered with community and faith-based organizations, patient groups, and others to educate the general public on the safety and effectiveness of the COVID-19 vaccines. These gains in our overall understanding of the value of vaccines must continue beyond COVID-19. We are very pleased to see Congress considering bills like H.R. 951, "Maternal Vaccinations Act;" H.R. 1550, "PREVENT HPV Cancers Act of 2021;" and H.R. 3742, the "Vaccine Information for Nursing Facility Operators Act." Broader outreach to populations at higher risk for vaccine-preventable diseases will help increase immunization rates and could prevent illness, medical visits, hospitalizations, and deaths. We also are supportive of H.R. 3743, "Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act." During the pandemic, the Reagan-Udall Foundation conducted excellent market research and shared messages that could be used with various populations about the importance of the COVID-19 vaccines. This research was used by many as part of educational outreach efforts to communities of color, seniors, and others at risk for COVID-19 illness. The research generated by Reagan-Udall help stakeholders combat vaccine hesitancy with proven statements and information that resonate with specific populations.

I believe that the most important lesson we have learned relates to access to vaccination. As the U.S. government rolled out the COVID-19 vaccines, we came to realize the many different barriers to access within our healthcare system, especially for people of color, seniors and those living in rural areas. Many at-risk people who wanted vaccines would have faced both financial and logistical impediments had Congress not acted. Legislation passed during the pandemic ensured the COVID-19 vaccines were covered at no cost to all Americans and could be given in many different settings.

Beyond the pandemic, two bipartisan bills will help reduce financial barriers to immunizations for Americans of all ages by addressing the last few areas where cost-sharing is still applied for vaccines. Cost-sharing for vaccines simply makes no sense. Vaccines are currently the only source of primary prevention, meaning they **prevent** a person from getting sick **and** also keep them from making **others** sick. This is why they generate such high societal benefits in terms of productivity and healthcare cost reductions. Yet two key populations still face copayments for vaccines: Medicare and Medicaid beneficiaries.

H.R. 1978, the Protecting Seniors Through Immunization Act of 2021, would eliminate cost-sharing in Medicare Part D for all CDC-recommended vaccines. Currently seniors pay copayments only on those vaccines covered under Medicare Part D (tetanus-diphtheria-acellular pertussis (Tdap) and varicella zoster (shingles)). And these co-pays vary widely across plans. This significant legislation will bring much needed parity to the out-of-pocket payment required of Medicare beneficiaries for vaccines covered under Part D, making it the same as those vaccines covered under Part B. Immunizations should be available with no cost to the beneficiary in the same way vaccines are covered under Part B (Covid-19, influenza, pneumococcal) and under private insurance through the Affordable Care Act (ACA). Removing this barrier will provide a direct financial and health benefit for people aged 65 and over and will help to improve access and equity among the Medicare population.

H.R. 2170, the "Helping Adults Protect Immunity Act" (HAPI Act), also addresses cost-sharing for another population that suffers from access and equity issues, adults in state Medicaid programs. Infectious diseases often exacerbate underlying conditions making recovery longer and resulting in enduring negative health outcomes. COVID-19 made this point extremely clear. The worst outcomes from this highly transmissible respiratory infection hit communities of color, those with long-term underlying health conditions and those in occupations that could not be done at home. Many of the individuals in these populations are uninsured, underinsured, or are covered by Medicaid. The intersection of these populations highlighted the inequities in our healthcare system which must be addressed through many different policies. For vaccines, removing financial barriers is the first step to improving access and increasing uptake for at-risk adults. In addition, not all states cover all ACIP-recommended vaccines and those that do might have copayment requirements that discourage access to this important preventive service. Passage of the HAPI Act will provide equitable vaccines coverage to help reach more Americans who will benefit the most from vaccination.

One of the other important issues in supporting vaccination is the issue of patient safety. Vaccines are one of the safest medical interventions but there are still some who experience adverse events. Vaccine injuries are exceptionally rare – the U.S. Health Resources and Services Administration (HRSA) estimates that for every 1 million doses of vaccines that were distributed, approximately one individual was

compensated for an injury by the program². For those who have been injured, the U.S. has one of the most comprehensive compensation systems. The National Vaccine Injury Compensation Program (VICP) was established by Congress in 1986 as a no-fault alternative to the traditional tort system to make it quicker, cheaper, and easier for those who are injured by vaccines. The program currently covers any vaccine routinely administered to children and pregnant women. Vaccine manufacturers pay a \$0.75 per dose excise tax, which funds the program. The Vaccine Injury Compensation Modernization Act (H.R. 3655) would update and strengthen the program such that those injured by a vaccine can be more adequately compensated. Importantly, the legislation would also extend protection to adult vaccines in addition to those for children and pregnant women.

BIO also supports the other bills being considered by the Committee related to vaccines. Bill H.R. 2347, Strengthening the Vaccines for Children Act of 2021 will extend coverage of the VFC program to children enrolled in state CHIP programs, allowing currently uninsured children and adolescents to receive doses free of charge in their medical home. Three other bills – H.R. 979, H.R. 1452 and H.R. 3013 will help with equitable access to COVID-19 vaccines by ensuring evidence-based allocation of resources and providing transportation assistance to those who need it.

BIO and our member companies are excited to see such an extensive array of bipartisan legislation focused on vaccines, vaccination and public health. The policies put forward by these bills can dramatically impact access to and uptake of vaccines across people of all ages, races, ethnicities, and disease states. Achieving higher immunization rates for all Americans is the foundation of a healthier population and strengthens our national resilience and our ability to respond and recover from outbreaks or the next pandemic. As importantly, increasing immunization access can stimulate innovation in the research and development of new vaccines that tackle unmet medical needs. Vaccines that could prevent respiratory syncytial virus (RSV), HIV, tuberculosis, malaria, influenza and many other infectious diseases are already in the overall vaccine platform. Other technologies, such as monoclonal antibodies, offer yet another solution to meeting our unmet prevention needs. These novel products could allow us to protect millions more rapidly for several complicated infectious diseases. Ensuring that all of the populations who could benefit from these protections can access them will encourage investment by vaccine developers of all sizes and could lead to more vaccine innovators, more vaccine options and more healthcare savings not just in the United States but around the world.

² <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-report.pdf>

